510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k051841

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative, lateral flow immunoassay

E. Applicant:

WHPM, Inc.

F. Proprietary and Established Names:

WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test

G. Regulatory Information:

1. Regulation section:

   21 CFR section 862.1155 Human chorionic gonadotropin test system

2. Classification:

   Class II

3. Product code:

   JHI

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. For Laboratory Professional Use Only.

2. Indication(s) for use:

   The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. For Laboratory Professional Use Only.

3. Special conditions for use statement(s):

   For Laboratory Professional Use Only

4. Special instrument requirements:

   None

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I. Device Description:

Each WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test kit contains 25 sealed foil pouches. Each pouch contains a test device and a disposable plastic dropper. The test device contains goat polyclonal anti-HCG coated membrane and a pad containing dye-conjugated mouse monoclonal anti-HCG in a protein matrix with 0.1% sodium azide.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACON Laboratories, Inc. HCG One Step Pregnancy Test (Urine/Serum)

2. Predicate 510(k) number(s):

   k993065

3. Comparison with predicate:

Deleted: ¶

Similarities		
Item	k051841	Predicate: ACON k993065
Intended Use	One-step test for qualitative detection of hCG in urine or serum; for Laboratory Professional Use	Same
Test Principle	Lateral flow immunoassay	Same
Result read time	3 minutes for urine 5 minutes for serum	Same
Sample type	Urine or serum	Urine or serum
Sensitivity	25 mIU/mL	25 mIU/mL

K. Standard/Guidance Document Referenced (if applicable):

Deleted: t applicable

None referenced

L. Test Principle:

The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy test employs a combination of dye conjugated monoclonal antibody and polyclonal solid phase antibody to selectively identify hCG in serum and urine. The sample (~100 µL) is added to the specimen well of the test device using the specimen dropper provided. As the sample flows through the absorbent portion of the device, the antibody-dye conjugate binds to the hCG if it is present in the sample, forming an antibody-antigen complex. The complex binds to the anti-hCG antibody in the reaction zone, producing a pink-rose colored band in the test area when the concentration of hCG is equal to or greater than 25 mIU/mL. Absence of a colored line indicates a negative result. A colored line should also appear in the control area of the device, to indicate the test was performed correctly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Reproducibility was confirmed by testing the device with three different levels

of spiked hCG in both male serum and urine: 0 (unspiked), 25 and 100 mIU/mL. For each test sample 12 replicates (n=12) were performed. The 0 mIU/mL serum and urine both gave negative results, while the 25 and 100 mIU/mL test sample in serum and urine all gave positive results.

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The assay was standardized using the hCG WHO 3rd International Standard 75/537.

Stability studies are on-going and are performed for each lot of product. A stability protocol was provided. The data generated to date support a shelf-life of 24 months when the product is stored at 2-30°C.

d. Detection limit:

Five male urine and five serum samples were each spiked with five concentrations of hCG (0, 10, 25, 50 and 100 mIU/mL) and tested. All the 0 and 10 mIU/mL test samples were negative while all of the 25, 50, and 100 mIU/mL test samples were positive. A 25 mIU/mL cutoff is claimed for serum and urine.

e. Analytical specificity:

Luteinizing hormone (500 mIU/mL), follicle stimulating hormone (1000 mIU/ml) and thyroid stimulating hormone (1000 µIU/mL) were added to hCG negative and hCG positive (25 mIU/mL hCG added) male serum and urine. The potential cross-reactants spiked into hCG negative serum and urine all gave negative results in the assay. The potential cross-reactants spiked into the sera and urines containing 25 mIU/mL hCG all gave positive results.

Common prescription and over the counter drugs, as well as hemoglobin, protein, bilirubin and triglycerides were also tested in the assay at specified concentrations, in both hCG negative and positive samples. The potential interferents were tested in both urine and serum, except for protein (urine only) and triglycerides (serum only). No interference was observed at the concentrations tested.

The Prozone or “hook” effect was studied by testing samples containing high concentrations of hCG using the assay. Urine and serum specimens from normal, non-pregnant donors were spiked with up to 1,000 IU/mL of hCG and tested. All test samples up to 1,000 IU/mL gave a positive result, indicating

the absence of a hook effect at this level or below.

f. Assay cut-off:

See (d) Detection Limit above

2. Comparison studies:

a. Method comparison with predicate device:

Matched urine and serum specimens from 102 individuals were tested using both the WH Accu Test and ACON Laboratories One Step Pregnancy test. The samples were obtained with informed consent from patients seeking confirmation of pregnancy. Of these specimens, 57 were positive and 45 negative with both the WH Accu Test and the predicate device.

b. Matrix comparison:

When comparing the 102 matched serum and urine specimens, there was 100% agreement using the WH Accu Test.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values are based on literature. The labeling states the following:

Negative results are expected in healthy, non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports substantial equivalence decision.